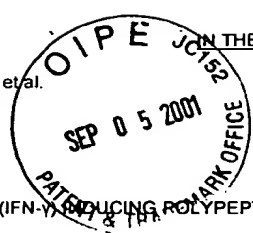


Box 591/1646



In Re Application of: USHIO et al.

Application No.: 09/716,356

Filed: November 21, 2000

For: INTERFERON-GAMMA (IFN- γ) INDUCING POLYPEPTIDE, PHARMACEUTICAL...

Art Unit: 1646

Examiner: D. Jiang

Washington, D.C.

Atty.'s Docket: USHIO=2

Date: September 5, 2001

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is a ☐ Amendment ☒ NOTICE TO COMPLY WITH SEQUENCE LISTING REQUIREMENTS
in the above-identified application.

- ☒ Small entity status of this application under 37 CFR 1.9 and 1.27 has been established by a verified statement previously submitted
- ☐ A verified statement to establish small entity status under 37 CFR 1.9 and 1.27 is enclosed.
- ☒ No additional fee.
- ☐ The fee has been calculated as shown below:

| | (Col. 1) | | (Col. 2) | (Col. 3) |
|---|---|-------|---------------------------------------|----------------------------|
| | CLAIMS REMAINING AFTER AMENDMENT | | HIGHEST NO. PREVIOUSLY PAID FOR | PRESENT EXTRA EQUALS |
| TOTAL | * | MINUS | ** 20 | 0 |
| INDEP. | * | MINUS | *** 3 | 0 |
| FIRST PRESENTATION OF MULTIPLE DEP. CLAIM | | | | |

ADDITIONAL FEE TOTAL

| SMALL ENTITY | |
|----------------------|-------------------|
| RATE | ADDITIONAL FEE |
| x 9 | \$ |
| x 40 | \$ |
| + 135 | \$ |
| ADDITIONAL FEE TOTAL | |
| \$ | |

| OTHER THAN SMALL ENTITY | |
|-------------------------|-------------------|
| RATE | ADDITIONAL FEE |
| x 18 | \$ |
| x 80 | \$ |
| + 270 | \$ |
| TOTAL | |
| \$ | |

- * If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.
- ** If the "Highest Number Previously Paid for" IN THIS SPACE is less than 20, write "20" in this space.
- *** If the "Highest Number Previously Paid for" IN THIS SPACE is less than 3, write "3" in this space.

The "Highest Number Previously Paid For" (total or independent) is the highest number found from the equivalent box in Col. 1 of a prior amendment of the number* of claims originally filed.

☒ Conditional Petition for Extension of Time

If any extension of time for a response is required, applicant requests that this be considered a petition therefor.

☐ It is hereby petitioned for an extension of time in accordance with 37 CFR 1.136(a). The appropriate fee required by 37 CFR 1.17 is calculated as shown below:

Small Entity
Response Filed Within

☐ First - \$ 55.00

☐ Second - \$ 195.00

☐ Third - \$ 445.00

☐ Fourth - \$ 695.00

Month After Time Period Set

Other Than Small Entity
Response Filed Within

☐ First - \$ 110.00

☐ Second - \$ 390.00

☐ Third - \$ 890.00

☐ Fourth - \$ 1390.00

Month After Time Period Set

☐ Less fees (\$) already paid for month(s) extension of time on

☐ Please charge my Deposit Account No. 02-4035 in the amount of \$


☐ Credit Card Payment Form, PTO-2038, is attached, authorizing payment in the amount of \$.

☐ A check in the amount of \$ is attached (check no.).

☒ The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035. This authorization and request is not limited to payment of all fees associated with this communication, including any Extension of Time fee, not covered by check or specific authorization, but is also intended to include all fees for the presentation of extra claims under 37 CFR \$1.16 and all patent processing fees under 37 CFR \$1.17 throughout the prosecution of the case. This blanket authorization does not include patent issue fees under 37 CFR \$1.18.

BROWDY AND NEIMARK

Attorneys for Applicant(s)

By: 
ALLEN C. YUN
Registration No. 37,971

Facsimile: (202) 737-3528
Telephone: (202) 628-5197



#8/02
E. H. H. D.
9-10-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ATTY.'S DOCKET: USHIO=2

| | | |
|------------------------------------|---|--------------------|
| In re Application of: |) | Art Unit: 1646 |
| |) | |
| USHIO et al. |) | Examiner: D. JIANG |
| |) | |
| Appln. No.: 09/716,356 |) | Washington, D.C. |
| |) | |
| Filed: November 21, 2000 |) | September 5, 2001 |
| |) | |
| For: INTERFERON- γ INDUCING |) | |
| POLYPEPTIDE, PHARMACEUTICAL |) | |
| COMPOSITION THEREOF, |) | |
| MONOCLONAL ANTIBODY THERETO, |) | |
| AND METHODS OF USE |) | |

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SEP 07 2001

RECEIVED

RESPONSE TO NOTICE TO COMPLY WITH
SEQUENCE LISTING REQUIREMENTS

Honorable Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Notice to Comply, dated August 9, 2001,
and prior to the examination of the above-described application,
please amend the present application as follows:

Applicants have added into the present specification a
substitute paper copy Sequence Listing section according to 37 C.F.R.
§1.821(c) as new pages 1-10. Furthermore, attached hereto is a 3 1/2"
disk containing the "Sequence Listing" in computer readable form in
accordance with 37 C.F.R. §1.821(e).

The following statement is provided to meet the
requirements of 37 C.F.R. §1.825(a) and 1.825(b).

I hereby state, in accordance with 37 C.F.R. §1.825(a),
that the amendments included in the substitute sheets of the sequence
listing are believed to be supported in the application as filed and

that the substitute sheets of the sequence listing are not believed to include new matter.

I hereby further state, in accordance with 37 C.F.R. §1.825(b), that the attached copy of the computer readable form is the same as the attached substitute paper copy of the sequence listing.

Under U.S. rules, each sequence must be classified in <213> as an "Artificial Sequence", a sequence of "Unknown" origin, or a sequence originating in a particular organism, identified by its scientific name.

Neither the rules nor the MPEP clarify the nature of the relationship which must exist between a listed sequence and an organism for that organism to be identified as the origin of the sequence under <213>.

Hence, counsel may choose to identify a listed sequence as associated with a particular organism even though that sequence does not occur in nature by itself in that organism (it may be, e.g., an epitopic fragment of a naturally occurring protein, or a cDNA of a naturally occurring mRNA, or even a substitution mutant of a naturally occurring sequence). Hence, the identification of an organism in <213> should not be construed as an admission that the sequence *per se* occurs in nature in said organism.

Similarly, designation of a sequence as "artificial" should not be construed as a representation that the sequence has no association with any organism. For example, a primer or probe may be designated as "artificial" even though it is necessarily complementary to some target sequence, which may occur in nature. Or an

"artificial" sequence may be a substitution mutant of a natural sequence, or a chimera of two or more natural sequences, or a cDNA (i.e., intron-free sequence) corresponding to an intron-containing gene, or otherwise a fragment of a natural sequence.

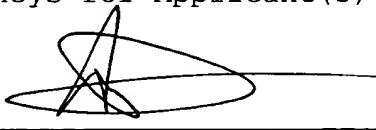
The Examiner should be able to judge the relationship of the enumerated sequences to natural sequences by giving full consideration to the specification, the art cited therein, any further art cited in an IDS, and the results of his or her sequence search against a database containing known natural sequences.

Applicants submit that the present application contains patentable subject matter and therefore urge the examiner to pass the case to issuance.

If the examiner has any questions or comments concerning the above described application, the examiner is urged to contact the undersigned at the phone number below.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By 

Allen C. Yun
Registration No. 37,971

ACY:pr
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528

F:\S\SUMA\USHIO2\pto\RESPONSE TO NOTICE TO COMPLY SEQ LIST NO.2.wpd

Notice to Comply

Application No.

09/716,356

Applicant(s)

Ushio et al

Examiner

DONG JIANG

Art Unit

1646

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s).

- ☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other:

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

PatentIn Software Program Support

Technical Assistance.....703-287-0200

To Purchase PatentIn Software.....703-306-2600

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